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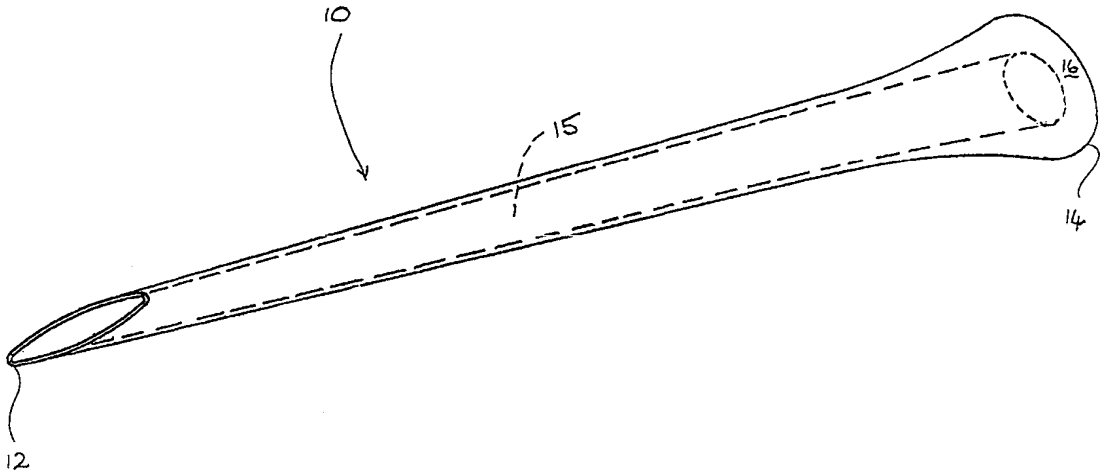

(57) **Abstract**

The present invention provides a microfistula tube including a soluble duct, defining a drainage canal having an inner surface, the duct being biocompatible, wherein the microfistula tube is coated with and/or incorporates biological cells for forming a basement membrane, or an intracellular matrix and a basement membrane. The biological cells may coat the inner surface of the drainage canal, and the microfistula tube may be made of a mouldable material or an absorbable material. The invention also provides an implantation system for the microfistula tube including a microfistula tube and a surgical instrument including an outer tube for penetrating body tissue, an inner tube, and an innermost rod, wherein the outer tube, the inner tube and the innermost rod are coaxial, the outer tube is adapted to receive said microfistula tube, whereby the inner tube may be used to push the microfistula tube into position and the innermost rod provides mechanical support during implantation of the microfistula tube.

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BIOLOGICAL MICROFISTULA TUBE AND IMPLANTATION METHOD AND APPARATUS

This invention relates to a microfistula tube for the creation of microfistulae within the body, to be used for example to drain unwanted aqueous fluid, and a method and apparatus for the insertion into the body of a microfistula tube. In a preferred embodiment the microfistula tube is used for drainage of excess fluid in the eye.

Existing devices for the drainage of excessive aqueous fluid within the body, and most especially to control intraocular pressure in advanced refractory glaucoma, have been made of materials such as horse-hair, silk thread, gold foil, autologous canaliculus, tantalum wire, glass, platinum, polymethylmethacrylate, polyethylene, gelatin and autologous cartilage. Various devices made of these materials have been inserted, for example, in the anterior chamber of the eye under a conjunctival or scleral flap extending into the anterior subconjunctival space. However, problems frequently associated with existing devices include foreign-body reactions leading to fibroblast proliferation and sub-conjunctival fibrosis formation around the posterior exit of the drainage implant. Commonly, existing devices require large incisions of 1 mm × 3 mm or even larger. Such incisions represent an extensive surgical injury and can lead to the formation of excessive quantities of scar tissue. Further, existing fistula tubes are mainly of non-biological materials and operate in far from physiological conditions. Such a fistula tube may generate an adverse tissue response, which causes blockage of the fistula tube resulting in uncontrolled eye pressure and ultimately negates any beneficial effects. More recent developments have attempted to protect the posterior exit of the drainage tube and develop posterior shunting of aqueous fluid to an equatorial sub-Tenon's collecting device.

These developments include a modified Krupin-Denver valve, the Schocket implant, the Joseph valve, and the Molteno implant.

An object of the present invention is to provide a biological microfistula tube subject to reduced rejection effects, that will lead to the formation of a microfistula for permanent or long-term aqueous fluid bypass, with minimal overdraining, and tending to impede wound healing processes and hence the closure of the drainage pathway. Further objects of the invention are to provide such a biological microfistula tube generating minimal tissue reaction, and matching outflow resistance, to allow the control of eye pressure and reduce surgical complications. A further object of the present invention is to provide a method and apparatus for the implantation of the biological microfistula tube.

According to a first broad aspect of the present invention there is provided a microfistula tube including:

a soluble duct, defining a drainage canal having an inner surface, the duct being biocompatible, wherein

said microfistula tube is coated with and/or incorporates biological cells for forming a basement membrane, or an intracellular matrix and a basement membrane.

Preferably the biological cells coat the inner surface of the drainage canal.

Preferably the microfistula tube is made of a mouldable material.

Preferably the microfistula tube is made of absorbable material.

Any suitable biocompatible material may be used, provided it permits the adherence of a basement membrane to the inner surface of the microfistula tube, and permits host endothelial or epithelial cells to grow in and coat the

inner surface, while permitting minimal tissue reaction. Thus, the microfistula tube may be placed into a body, but will be incorporated into surrounding tissue or absorbed by the body over time. The biological cells - whose type will depend on the location where the microfistula tube is implanted - will provide a biological lining of the drainage pathway (i.e. microfistula) formed within the body by the microfistula tube, and inhibit the wound healing processes that would tend to occlude the drainage pathway. These cells will also reduce rejection effects. The biological cells, which will eventually form a permanent or long-lived endothelial, epithelial or similar lining of the drainage pathway formed by the microfistula tube minimize the tendency for fibroblast proliferation and the occlusion of the pathway. Consequently a microfistula tube size smaller than has been feasible with prior art devices or techniques may be employed, thereby reducing the risk of overdraining the aqueous fluid.

Preferably the biological cells are endothelial or trabecular meshwork cells.
Preferably the microfistula tube is made of gelatin or collagen.

By using a substance such as gelatin or collagen the mechanical and absorption properties of the tube may readily be manipulated, and the microfistula tube given the required rigidity and absorption properties.

Preferably the microfistula tube is sufficiently rigid to allow ready insertion into a living body.
Preferably the microfistula tube is a tube with a circular cross-section.
Preferably the outer surface of the microfistula tube tapers towards its forward end to facilitate its insertion into body tissues. Thus, the microfistula tube may be narrower at the forward end so that it can more easily be

pushed into the relevant tissues of the body.

Preferably the duct is provided with one or more generally rearwardly projecting barbs or a generally rearwardly projecting skirt. Preferably the one or more barbs or said skirt is near the forward end of said microfistula tube. Thus, once the microfistula tube is in place it will not easily be able to move back along the path of insertion and hence be dislodged.

Preferably the rearward end of said microfistula tube has thicker walls to provide improved area and strength to allow the microfistula tube to be pushed into place by pressing against the rear end of the microfistula tube.

Preferably the rearward end of the microfistula tube has an increased outer perimeter size to prevent the microfistula tube from advancing beyond the point of implantation.

Thus, the rear end of the microfistula tube has an increased perimeter or, when the microfistula is tubular, an increased outer diameter, both to provide a broader base against which pressure may be applied to insert the microfistula tube into body tissues, and also to prevent the microfistula tube from advancing further than the point of implantation.

Preferably the microfistula tube is adapted to form a passage from the anterior chamber to Schlemm's canal, and has an interior diameter of between 100 and 200 μm, and a length of between 1 and 3 mm.

More preferably the microfistula tube has an interior diameter of approximately 150 μm and a length of approximately 2 mm.

Alternatively the microfistula tube is adapted to form a

passage from the anterior chamber to the anterior subconjunctival space and has an interior diameter of between 100 and 400 μm and a length of between 2 and 6 mm.

Preferably the microfistula tube has an interior diameter of between 250 and 350 μm.

More preferably the microfistula tube has an interior diameter of approximately 300 μm and a length of approximately 3 mm.

Alternatively the microfistula tube is adapted to form a passage from the anterior chamber to the episcleral vein, with an inner diameter of between 100 and 300 μm and a length of between 7 and 14 mm.

Preferably the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 10 mm.

In one embodiment the microfistula tube is adapted to form a passage from the vitreal cavity to the subarachnoid space of the optic nerve, and has an inner diameter of between 100 and 300 μm and a length of between 3 and 12 mm.

Preferably the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 6 mm.

Thus, the microfistula tube may be used in optical applications to shunt aqueous fluid from the anterior chamber into Schlemm's canal, the subconjunctival space, or the episcleral vein, or from the vitreal cavity to the subarachnoid space of the optic nerve.

According to second broad aspect of the present invention there is provided a microfistula tube implantation system including:

a microfistula tube as described above; and

a surgical instrument including an outer tube for penetrating body tissue,

an inner tube, and

an innermost rod,

wherein said outer tube, said inner tube and said innermost rod are coaxial, said outer tube is adapted to receive said microfistula tube, whereby the inner tube may be used to push the microfistula tube into position and the innermost rod provides mechanical support during implantation of the microfistula tube.

Thus, the outer tube can be used to penetrate body tissues (for example a cornea), and the inner tube can then be used to push the microfistula tube forward and out of the forward end of the outer tube. The innermost rod may be moved with the inner tube until the microfistula tube is in its final position, and then the innermost rod may be withdrawn, followed by the inner tube. The outer tube may then be withdrawn from the body.

Preferably said microfistula tube is adapted to receive said innermost rod.

Preferably the outer tube is a hypodermic-type tube.

Preferably the inner tube is blunt-ended.

Preferably the outer tube is of stainless steel.

Preferably the inner tube is of stainless steel.

Preferably the innermost rod is of tungsten.

Preferably the surgical instrument is adapted to be attached to an ultramicrosurgical system.

Preferably the surgical instrument is adapted to be

manipulated by electric motors.

Thus, the surgical instrument is adapted to deliver the microfistula tube to the required location. For greatest precision, the surgical instrument is used with a microsurgical system powered by electric motors and the operational procedures are performed under an operation microscope and gonioscopic observation.

According to third broad aspect of the present invention there is provided a microfistula tube implantation system including:

a microfistula tube as described above; and

a surgical instrument including an outer tube for cutting and penetrating body tissue, and

an inner rod,

wherein said outer tube and said inner rod are coaxial, said outer tube is adapted to receive said microfistula tube and said inner rod, and said outer tube has a sharp forward end for cutting body tissue, whereby the outer tube may be used to create a passage to an implantation site for said microfistula tube, said inner rod may be used to position a microfistula tube at said site, and said inner rod and outer tube may be withdrawn from said site leaving said microfistula tube in position at said site.

Preferably the outer tube is a hypodermic-type tube.

Preferably the outer tube is of stainless steel.

Preferably the inner rod is of stainless steel.

Preferably the surgical instrument is adapted to be attached to an ultramicrosurgical system.

Preferably the surgical instrument is adapted to be

manipulated by electric motors.

According to fourth broad aspect of the present invention there is provided a method for the implantation of a microfistula tube including:

introducing into the vicinity of a desired implantation location an implantation system as claimed in any one of claims 23 to 31 with said microfistula tube mounted on the innermost rod,

pushing the microfistula tube out of the outer tube and into a desired location by means of the inner tube, the rod moving in unison with the inner tube and the microfistula tube,

withdrawing the surgical instrument from the body.

Preferably the rod is withdrawn from the microfistula tube before the inner tube is withdrawn.

Preferably the rod and inner tube are withdrawn into the outer tube before the inner tube, outer tube and rod are withdrawn from the body.

Preferably the desired location is the anterior chamber.

According to fifth broad aspect of the present invention there is provided a method for the implantation of a microfistula tube including:

forming said passage with said outer tube of said implantation system as claimed in any one of claims 32 to 37 with said microfistula tube in said outer tube forward of said inner rod,

advancing said microfistula tube to said implantation site with said inner rod,

withdrawing said outer tube,

withdrawing said inner rod, and

withdrawing the surgical instrument.

Preferably the method includes withdrawing the outer tube partially, then withdrawing said inner rod partially, followed by withdrawing said inner rod and outer tube in unison.

Preferably the partial withdrawal of the outer tube continues until said forward of said outer tube is in the anterior chamber.

Preferably the method includes rotating said outer tube with a reciprocating motion while forming said passage to aid said cutting of said tissue.

Brief Description of the Drawings

Preferred embodiments of the invention will be described, by way of example, with reference to the accompanying drawings in which:

Figure 1 is a view of a microfistula tube embodying the present invention;

Figure 2 is a view of a microfistula tube and surgical instrument according to a further embodiment of the present invention;

Figure 3 illustrates a method for the implantation of a microfistula tube according to a further embodiment of the present invention;

Figure 4 is a further illustration of the method for the implantation of a microfistula tube shown in Figure 3, wherein a surgical instrument and microfistula tube are shown having penetrated a cornea;

Figure 5 shows a further stage in the method of Figure 3, in which a microfistula tube has been moved into its final position in the eye;

Figure 6 shows a further illustration of the method of Figure 3, in which the supporting rod is shown withdrawn from the microfistula tube;

Figure 7 is a further illustration of the method of Figure 3, in which the inner tube and supporting rod are shown retracted into the outer hypodermic-type tube;

Figure 8 is a further illustration of the method of Figure 3, in which the completed method is shown with the microfistula tube implanted in the eye and the surgical instrument removed from the cornea;

Figure 9 is a view of a surgical instrument and microfistula tube according to a further embodiment of the present invention;

Figure 10 is a view of a method of implantation of the microfistula tube by means of the surgical instrument of Figure 9, wherein the surgical instrument and microfistula tube are shown having penetrated a cornea;

Figure 11 shows a further stage in the method of Figure 10, in which the surgical instrument has been advanced to the subconjunctival space;

Figure 12 shows a further illustration of the method of Figure 10, in which the microfistula tube has been advanced to an implantation site;

Figure 13 is a further illustration of the method of Figure 10, in which the outer tube of the surgical instrument has been withdrawn to the anterior space; and

Figure 14 is a further illustration of the method of Figure 10, in which the nearly completed method is shown with the microfistula tube implanted in the eye and the surgical instrument withdrawn to the anterior space.

Detailed Description of the Preferred Embodiments

A biological microfistula tube according to the present invention is shown generally at 10 in Figure 1. The microfistula tube 10 comprises a hollow tube which defines a drainage canal 15 with a forward end 12 terminating in a point to facilitate the penetration by the microfistula tube 10 of tissue and a rear end 14. The rear end 14 of the microfistula tube 10 has thickened walls to strengthen

the microfistula tube 10, as implantation of the microfistula tube 10 will generally be performed by pushing the microfistula tube 10 into place by applying pressure to the rear end 14.

The microfistula tube 10 is made from gelatin, as the mechanical and absorption properties of the gelatin can be manipulated by varying the degree of cross-linking and controlling the water content. The material can therefore be designed to have the required rigidity to withstand the implantation process, but be absorbed after a controllable period. In most instances this would be only a matter of days or weeks.

The microfistula tube incorporates biological cells. Such cells lead to the formation of a biological lining of the drainage canal, which inhibits the wound-healing processes that would tend to occlude the drainage pathway. These cells (not shown) are either endothelial cells or ocular trabecular meshwork cells. These cells would generally line the inner surface of the microfistula tube 10, though other configurations are possible, such as incorporating the cells into the material of the microfistula tube 10.

Optionally, the microfistula tube 10 can be provided with one or more rearward pointing barbs (not shown), preferably located near the forward end 12 and on the outer surface of the microfistula tube 10. These barbs would resist the unwanted rearward movement of the microfistula tube 10 following implantation. The flared rear end 14 of the microfistula tube 10, and the generally tapered profile of the microfistula tube 10, will resist unwanted forward movement of the microfistula tube 10. The thickening of the rear end 14 of the microfistula tube 10 can be extended forward some distance to further resist unwanted forward motion of the microfistula tube 10 after implantation. This thickened portion of the rearward end 14 may be

terminated more abruptly than shown in Figure 1, so that a substantially forward facing surface is provided for this purpose. Finally, the rearward pointing face 16 of the rear end 14 of the microfistula tube 10 may be recessed or otherwise adapted to receive the forward end of a surgical instrument, to facilitate implantation of the microfistula tube 10 by means of such an instrument.

A surgical instrument according to the present invention provided with a microfistula tube 10 is shown generally at 30 in Figure 2. The surgical instrument 30 shown in the Figure is adapted for the implantation of the microfistula tube 10 into the eye to form a drainage pathway from the anterior chamber to the subconjunctival space. The microfistula tube 10 shown in the Figure includes rearward pointing barbs and a recessed base, as discussed above. The surgical instrument 30 comprises an outer tube 32 in the form of a hypodermic-type stainless steel tube, an inner tube 34 in the form of a blunt-ended stainless steel tube, and an innermost rod 36 made of tungsten. The microfistula tube 10 is shown located around the forward end 38 of the innermost rod 36. The innermost rod 36 may slide within the inner tube 34, and the inner tube 34 may slide within the outer tube 32.

The outer tube 32 is adapted to penetrate the cornea, while the inner tube 34 is adapted to push the microfistula tube 10 from the outer tube 32 and into its final position. The innermost rod 36 is adapted to provide mechanical support during the implantation of the microfistula tube 10.

In use, the surgical instrument 30 would be attached to and manipulated by means of an ultramicrosurgical system, and the operation performed under an operation microscope and gonioscopic observation. All movement would be produced by electric motor.

It should be noted that the outer tube 32 is sharp at its forward end 40 to facilitate the penetration of the cornea. The inner tube 34 is rounded at its forward end 42, and the rear end of the microfistula tube 10 has a corresponding recess, so that the end 42 of the inner tube 34 may be received by the base of the microfistula tube 10.

A surgical implantation method according to the present invention is illustrated in Figures 3 to 8. The method illustrated in these figures is for the implantation of a microfistula tube to form a passage, by way of the drainage canal 15, between the anterior chamber 50 (see Figures 3 to 8) and the anterior subconjunctival space 52 (see Figures 3 to 8). The entry point is 2 mm anterior to the limbus on the temporal side (see Figure 3). This entry point may also be a pivot point of an ultramicrosurgical system, if such a system is used to manipulate the surgical instrument.

The surgical instrument 30 provided with a microfistula tube 10 penetrates the cornea 48, and enters the anterior chamber 50 (see Figure 4). The insertion of the surgical instrument 30 continues until the outer tube 32 of the surgical instrument 30 reaches the centre of the pupil 55.

The inner tube 34, the innermost rod 36, and the microfistula tube 10 are advanced further (see Figure 5), until the innermost rod 36 with the microfistula tube 10 penetrates the trabecular meshwork and sclera 57 until the tip of the microfistula tube 10 reaches the subconjunctival space 52. The innermost rod 36 is then withdrawn from the microfistula tube 10 (Figure 6), and the innermost rod (now withdrawn into the inner tube 34) and the inner tube 34 are retracted into the outer tube 32 (Figure 7).

Finally, the surgical instrument 30 is withdrawn from the eye, leaving the implanted microfistula tube 10 in position

(Figure 8). In practice, a suture would generally then be placed to close the corneal wound.

In this procedure, the microfistula tube 10 has an inner diameter of 100 μm and a length of 3 mm. In alternative embodiments, the microfistula tube 10 can be implanted to form a passage between the anterior chamber and Schlemm's canal, in which case the inner diameter of the microfistula tube 10 is 150 μm and its length is 2 mm. In another embodiment the microfistula tube 10 forms a passage between the anterior chamber and the episcleral vein, and has an inner diameter of 150 μm and a length of 10 mm. Alternatively, a microfistula tube of inner diameter 150 μm and length 6 mm may be used to form a passage from the vitreal cavity to subarachnoid space of the optic nerve.

In some embodiments of the present invention, when the inner tube 34, the innermost rod 36, and the microfistula tube 10 are advanced as shown in Figure 5, the resistance to penetration of the surrounding tissues may be so high that the microfistula tube cannot penetrate these tissues and collapses under the force of the inner tube 34. It may be preferable, therefore, to provide the outer tube at its forward end with a sharp end for cutting through the surrounding tissue. Referring to Figure 9, which is a view of an alternative embodiment of the implantation system of the present invention, outer tube 60 is again a hypodermic-type stainless steel tube. Unlike outer tube 32 of the embodiment illustrated in Figure 2, however, the forward end 62 of outer tube 60 is sharpened and the opening 64 at the forward end 62 faces forwardly rather than obliquely. Stainless steel inner rod 66 is provided within outer tube 60 and microfistula tube 68 is positioned forward of inner rod 66. Microfistula tube 68 will generally be substantially identical to those described above, but may lack the reinforced base of the above embodiments.

A method of implantation of a microfistula tube by means of this embodiment of the surgical instrument is illustrated in Figures 10 to 14. The method illustrated in these figures is again for the implantation of a microfistula tube between the anterior chamber and the anterior subconjunctival space. Referring to Figure 10, outer tube 60 is preferably rotated to assist the cutting of body tissues. This rotation alternates rapidly in direction so that tissue is cut by the tube 60. The outer tube 60 penetrates the cornea 48, and enters the anterior chamber 50. Inner rod 66 is not rotated during this insertion of the instrument or subsequently. Inner rod 66 and microfistula tube 68 are advanced with outer tube 60 until the forward end 62 of outer tube 60 reaches subconjunctival space 52 (see Figure 11).

Referring to Figure 12, the inner rod 66 is then advanced within outer tube 60, propelling microfistula tube 68 forward until microfistula tube 68 is adjacent to or extending marginally beyond the end 62 of outer tube 60. Referring to Figure 13, outer tube 60 is withdrawn from the immediate vicinity of the subconjunctival space 52, with inner rod 66 held stationary, until microfistula tube 68 is entirely released from the outer tube 60. The inner rod 66 prevents outer tube 60 from withdrawing the microfistula tube 68 during this step, after the completion of which the forward end 62 of outer tube 60 is in the anterior chamber 50.

Finally, the outer tube 60 and inner rod 66 (see Figure 14) are withdrawn from the body together, leaving the microfistula tube 68 at the implantation site.

Modifications within the spirit and scope of the invention may readily be effected by persons skilled in the art. For example, microfistula tubes may be adapted for use in other parts of the body where there is obstructed flow of fluid

and/or high fluid pressure, with appropriate dimensions and corresponding surgical instrumentation. Possible other sites include the cranium (to treat raised intracranial pressure), shunting from the subarachnoid space to one of the head or neck veins, incorporating in the microfistula tube a material favouring the growth of venous or subarachnoid space endothelial cells, or - in the treatment of Menière's Disease - the invention may be used to shunt from endolymph to perilymph in the inner ear using a material favourable to the growth of subarachnoid endothelial cells. Further, such biological microfistula tubes may be useful in surgery upon the ureter or urethra, to overcome obstructions or strictures, using material favourable to the growth of urogenital epithelial cells. In addition, although the surgical instrument described above has been designed for the implantation of microfistula tubes, it may also be adapted for use for the implantation of other surgical or medical devices. Consequently, it is to be understood that this invention is not limited to the particular embodiments described by way of example hereinabove.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A microfistula tube including:

a soluble duct, defining a drainage canal having an inner surface, the duct being biocompatible, wherein

said microfistula tube is coated with and/or incorporates biological cells for forming a basement membrane, or an intracellular matrix and a basement membrane.

2. A microfistula tube as claimed in claim 1 wherein the biological cells coat the inner surface of the drainage canal.

3. A microfistula tube as claimed in either claim 1 or 2 wherein the microfistula tube is made of a mouldable material.

4. A microfistula tube as claimed in any one of the preceding claims wherein the microfistula tube is made of absorbable material.

5. A microfistula tube as claimed in any one of the preceding claims wherein the biological cells are endothelial or trabecular meshwork cells.

6. A microfistula tube as claimed in any one of the preceding claims wherein the microfistula tube is made of gelatin or collagen.

7. A microfistula tube as claimed in any one of the preceding claims wherein the microfistula tube is sufficiently rigid to allow ready insertion into a living body.

8. A microfistula tube as claimed in any one of the preceding claims wherein the microfistula tube is a tube with a circular cross-section.

9. A microfistula tube as claimed in any one of the preceding claims wherein the outer surface of the microfistula tube tapers towards its forward end to facilitate its insertion into body tissues.

10. A microfistula tube as claimed in any one of the preceding claims wherein the duct is provided with one or

more generally rearwardly projecting barbs or a generally rearwardly projecting skirt.

11. A microfistula tube as claimed in claim 10 wherein said one or more barbs or said skirt is near the forward end of said microfistula tube.

12. A microfistula tube as claimed in any one of the preceding claims wherein the rearward end of said microfistula tube has thicker walls to provide improved area and strength to allow the microfistula tube to be pushed into place by pressing against the rear end of the microfistula tube.

13. A microfistula tube as claimed in any one of the preceding claims wherein the rearward end of the microfistula tube has an increased outer perimeter size to prevent the microfistula tube from advancing beyond the point of implantation.

14. A microfistula tube as claimed in any one of the preceding claims wherein the microfistula tube is adapted to form a passage from the anterior chamber to Schlemm's canal, and has an interior diameter of between 100 and 200 μm, and a length of between 1 and 3 mm.

15. A microfistula tube as claimed in claim 14 wherein the microfistula tube has an interior diameter of approximately 150 μm and a length of approximately 2 mm.

16. A microfistula tube as claimed in any one of claims 1 to 13 wherein the microfistula tube is adapted to form a passage from the anterior chamber to the anterior subconjunctival space and has an interior diameter of between 100 and 400 μm and a length of between 2 and 6 mm.

17. A microfistula tube as claimed in claim 16 wherein the microfistula tube has an interior diameter of between 250 and 350 μm.

18. A microfistula tube as claimed in either claim 16 or 17 wherein the microfistula tube has an interior diameter of approximately 300 μm and a length of approximately 3 mm.

19. A microfistula tube as claimed in any one of claims 1 to 13 wherein the microfistula tube is adapted to form a

passage from the anterior chamber to the episcleral vein, with an inner diameter of between 100 and 300 μm and a length of between 7 and 14 mm.

20. A microfistula tube as claimed in claim 19 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 10 mm.

21. A microfistula tube as claimed in any one of claims 1 to 13 wherein the microfistula tube is adapted to form a passage from the vitreal cavity to the subarachnoid space of the optic nerve, and has an inner diameter of between 100 and 300 μm and a length of between 3 and 12 mm.

22. A microfistula tube as claimed in claim 21 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 6 mm.

23. A microfistula tube implantation system including:

a microfistula tube as claimed in any of the preceding claims; and

a surgical instrument including an outer tube for penetrating body tissue,

an inner tube, and

an innermost rod,

wherein said outer tube, said inner tube and said innermost rod are coaxial, said outer tube is adapted to receive said microfistula tube, whereby the inner tube may be used to push the microfistula tube into position and the innermost rod provides mechanical support during implantation of the microfistula tube.

24. A microfistula tube implantation system as claimed in claim 23, wherein said microfistula tube is adapted to receive said innermost rod.

25. A microfistula tube implantation system as claimed in either claim 23 or 24 wherein the outer tube is a hypodermic-type tube.

26. A microfistula tube implantation system as claimed in any one of claims 23 to 25 wherein the inner tube is blunt-ended.

27. A microfistula tube implantation system as claimed in

any one of claims 23 to 26 wherein the outer tube is of stainless steel.

28. A microfistula tube implantation system as claimed in any one of claims 23 to 27 wherein the inner tube is of stainless steel.

29. A microfistula tube implantation system as claimed in any one of claims 23 to 28 wherein the innermost rod is of tungsten.

30. A microfistula tube implantation system as claimed in any one of claims 23 to 29 wherein the surgical instrument is adapted to be attached to an ultramicrosurgical system.

31. A microfistula tube implantation system as claimed in any one of claims 23 to 30 wherein the surgical instrument is adapted to be manipulated by electric motors.

32. A microfistula tube implantation system including:

a microfistula tube as claimed in any one of claims 1 to 22; and

a surgical instrument including an outer tube for cutting and penetrating body tissue, and

an inner rod,

wherein said outer tube and said inner rod are coaxial, said outer tube is adapted to receive said microfistula tube and said inner rod, and said outer tube has a sharp forward end for cutting body tissue, whereby the outer tube may be used to create a passage to an implantation site for said microfistula tube, said inner rod may be used to position a microfistula tube at said site, and said inner rod and outer tube may be withdrawn from said site leaving said microfistula tube in position at said site.

33. A microfistula tube implantation system as claimed in claim 32 wherein the outer tube is a hypodermic-type tube.

34. A microfistula tube implantation system as claimed in either claim 32 or 33 wherein the outer tube is of stainless steel.

35. A microfistula tube implantation system as claimed in any one of claims 32 to 34 wherein the inner rod is of

stainless steel.

36. A microfistula tube implantation system as claimed in any one of claims 32 to 35 wherein the surgical instrument is adapted to be attached to an ultramicrosurgical system.

37. A microfistula tube implantation system as claimed in any one of claims 32 to 36 wherein the surgical instrument is adapted to be manipulated by electric motors.

38. A method for the implantation of a microfistula tube including:

introducing into the vicinity of a desired implantation location an implantation system as claimed in any one of claims 23 to 31 with said microfistula tube mounted on the innermost rod,

pushing the microfistula tube out of the outer tube and into a desired location by means of the inner tube, the rod moving in unison with the inner tube and the microfistula tube,

withdrawing the surgical instrument from the body.

39. A method as claimed in claim 38 wherein the rod is withdrawn from the microfistula tube before the inner tube is withdrawn.

40. A method as claimed in either claim 38 or 39 wherein the rod and inner tube are withdrawn into the outer tube before the inner tube, outer tube and rod are withdrawn from the body.

41. A method as claimed in any one of claims 38 to 40 wherein the desired location is the anterior chamber.

42. A method as claimed in any one of claims 38 to 41 wherein the microfistula tube is adapted to form a passage from the anterior chamber to Schlemm's canal, and has an interior diameter of between 100 and 200 μm, and a length of between 1 and 3 mm.

43. A method as claimed in claim 42 wherein the microfistula tube has an interior diameter of approximately 150 μm and a length of approximately 2 mm.

44. A method as claimed in any one of claims 38 to 41

wherein the microfistula tube is adapted to form a passage from the anterior chamber to the anterior subconjunctival space and has an interior diameter of between 100 and 400 μm and a length of between 2 and 6 mm.

45. A method as claimed in claim 44 wherein the microfistula tube has an interior diameter of between 250 and 350 μm.

46. A method as claimed in either claim 44 or 45 wherein the microfistula tube has an interior diameter of approximately 300 μm and a length of approximately 3 mm.

47. A method as claimed in any one of claims 38 to 41 wherein the microfistula tube is adapted to form a passage from the anterior chamber to the episcleral vein, with an inner diameter of between 100 and 300 μm and a length of between 7 and 14 mm.

48. A method as claimed in claim 47 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 10 mm.

49. A method as claimed in any one of claims 38 to 41 wherein the microfistula tube is adapted to form a passage from the vitreal cavity to the subarachnoid space of the optic nerve, and has an inner diameter of between 100 and 300 μm and a length of between 3 and 12 mm.

50. A method as claimed in claim 49 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 6 mm.

51. A method for the implantation of a microfistula tube including:

forming said passage with said outer tube of said implantation system as claimed in any one of claims 32 to 37 with said microfistula tube in said outer tube forward of said inner rod,

advancing said microfistula tube to said implantation site with said inner rod,

withdrawing said outer tube,

withdrawing said inner rod, and

withdrawing the surgical instrument.

52. A method as claimed in claim 51 including withdrawing the outer tube partially, then withdrawing said inner rod partially, followed by withdrawing said inner rod and outer tube in unison.

53. A method as claimed in claim 52 wherein said partial withdrawal of the outer tube continues until said forward of said outer tube is in the anterior chamber.

54. A method as claimed in any one of claims 51 to 53 including rotating said outer tube while forming said passage to aid said cutting of said tissue.

55. A method as claimed in any one of claims 51 to 54 wherein the microfistula tube is adapted to form a passage from the anterior chamber to Schlemm's canal, and has an interior diameter of between 100 and 200 μm, and a length of between 1 and 3 mm.

56. A method as claimed in claim 55 wherein the microfistula tube has an interior diameter of approximately 150 μm and a length of approximately 2 mm.

57. A method as claimed in any one of claims 51 to 54 wherein the microfistula tube is adapted to form a passage from the anterior chamber to the anterior subconjunctival space and has an interior diameter of between 100 and 400 μm and a length of between 2 and 6 mm.

58. A method as claimed in claim 57 wherein the microfistula tube has an interior diameter of between 250 and 350 μm.

59. A method as claimed in either claim 57 or 58 wherein the microfistula tube has an interior diameter of approximately 300 μm and a length of approximately 3 mm.

60. A method as claimed in any one of claims 51 to 54 wherein the microfistula tube is adapted to form a passage from the anterior chamber to the episcleral vein, with an inner diameter of between 100 and 300 μm and a length of between 7 and 14 mm.

61. A method as claimed in claim 60 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 10 mm.

62. A method as claimed in any one of claims 51 to 54 wherein the microfistula tube is adapted to form a passage from the vitreal cavity to the subarachnoid space of the optic nerve, and has an inner diameter of between 100 and 300 μm and a length of between 3 and 12 mm.

63. A method as claimed in claim 62 wherein the microfistula tube has an inner diameter of approximately 150 μm and a length of approximately 6 mm.

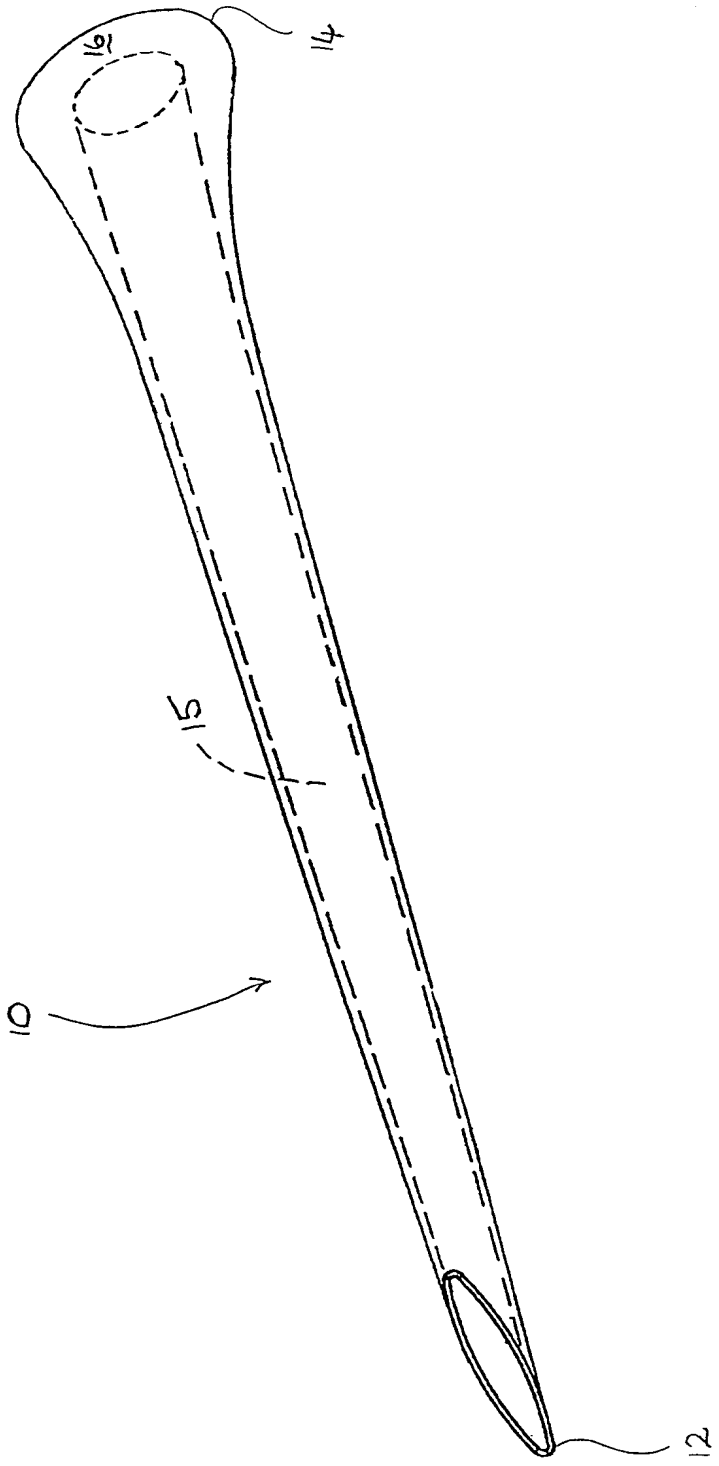


FIGURE 1

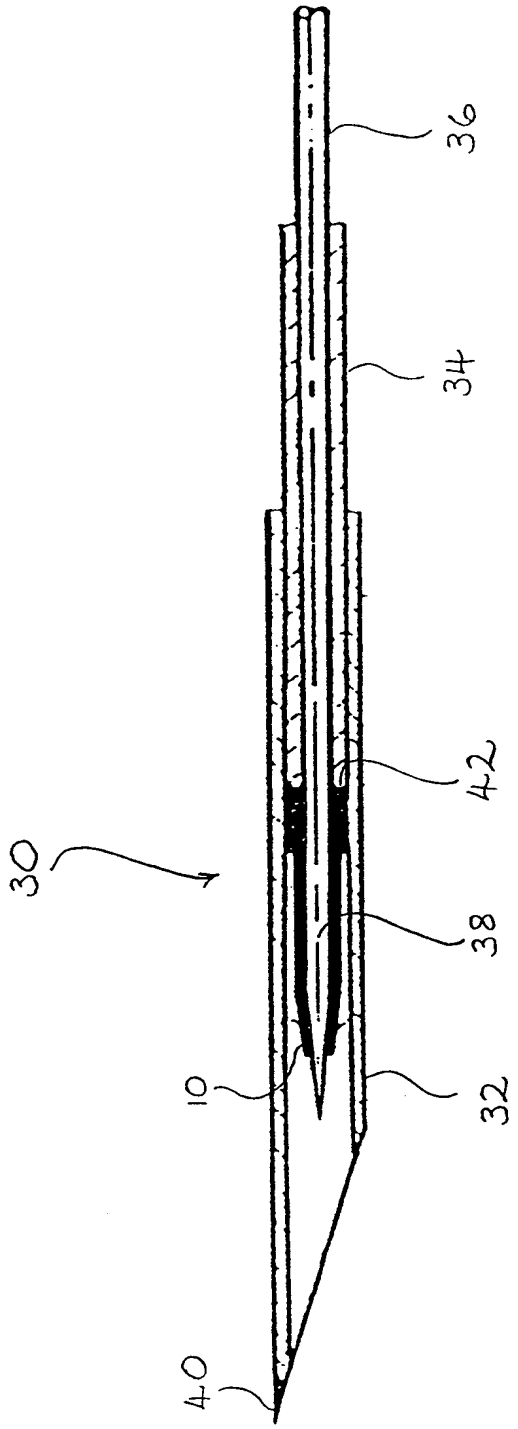


FIGURE 2

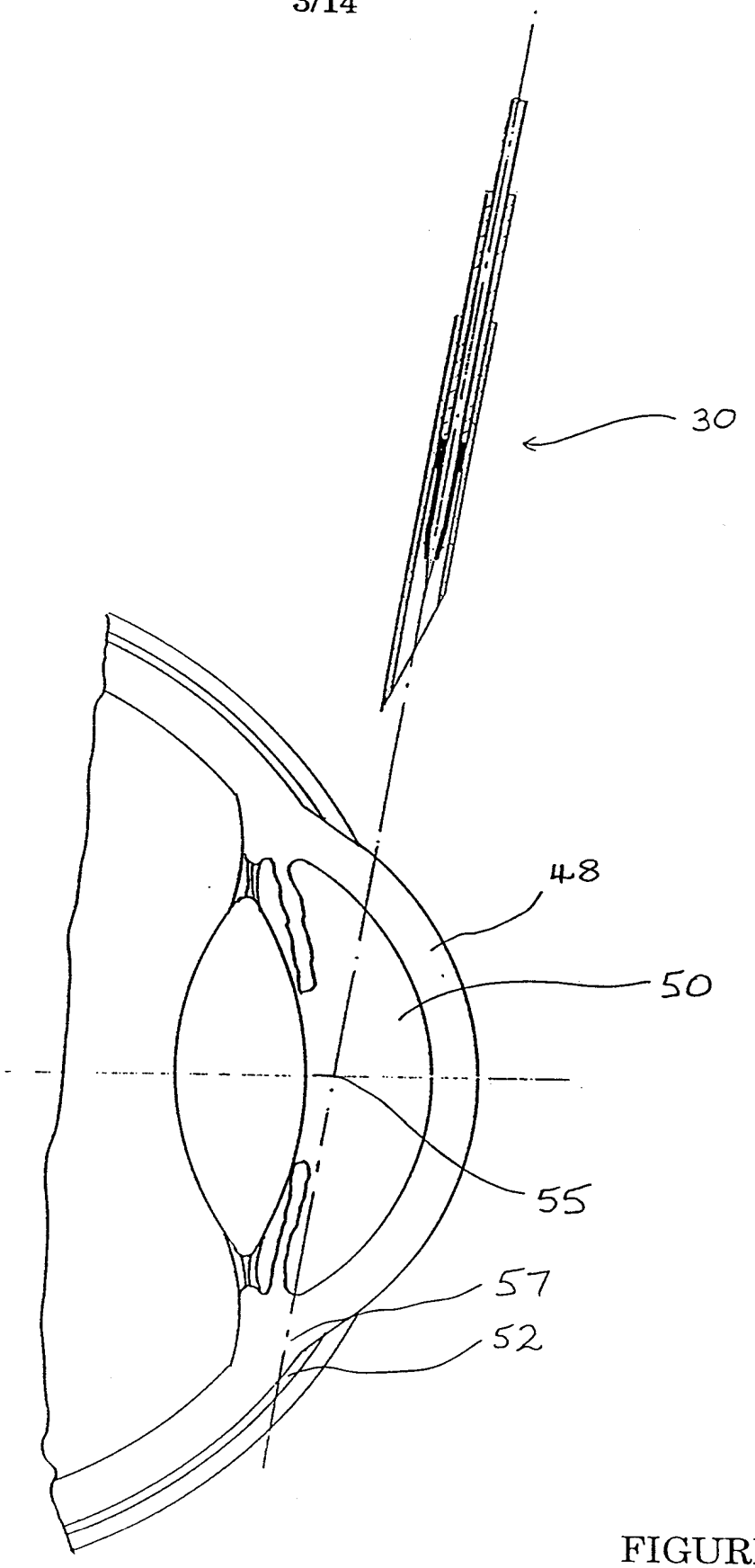


FIGURE 3

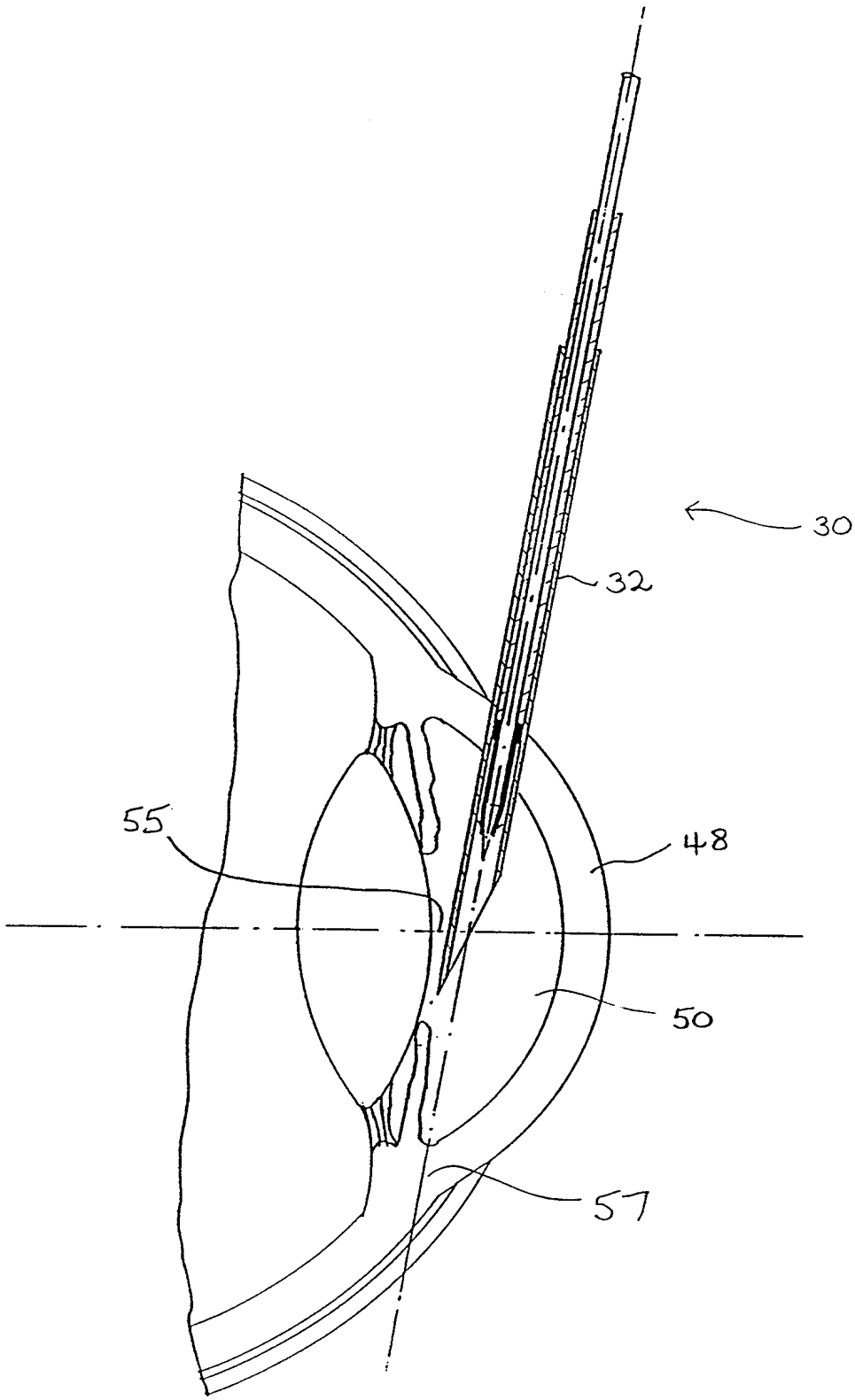


FIGURE 4

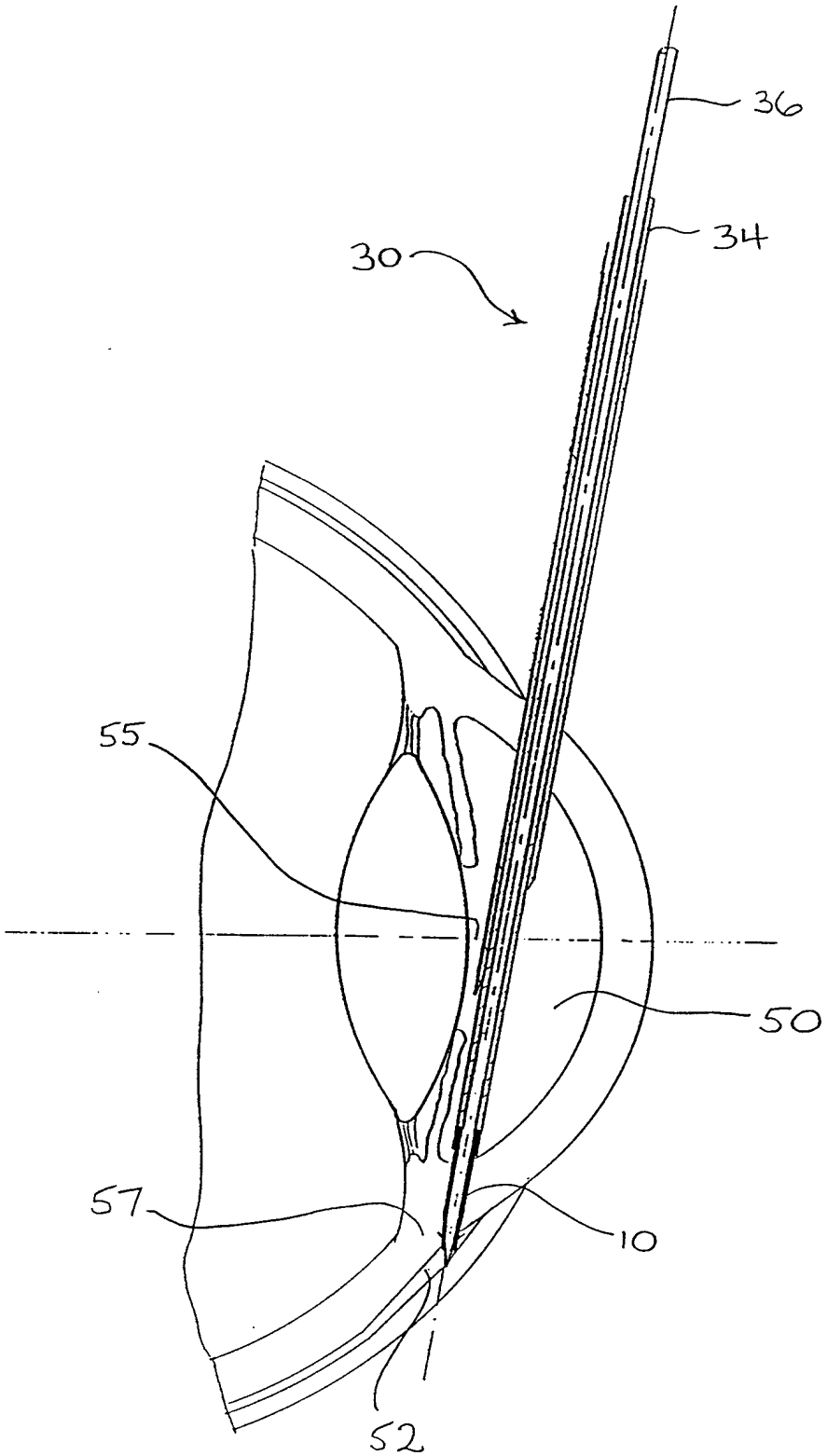
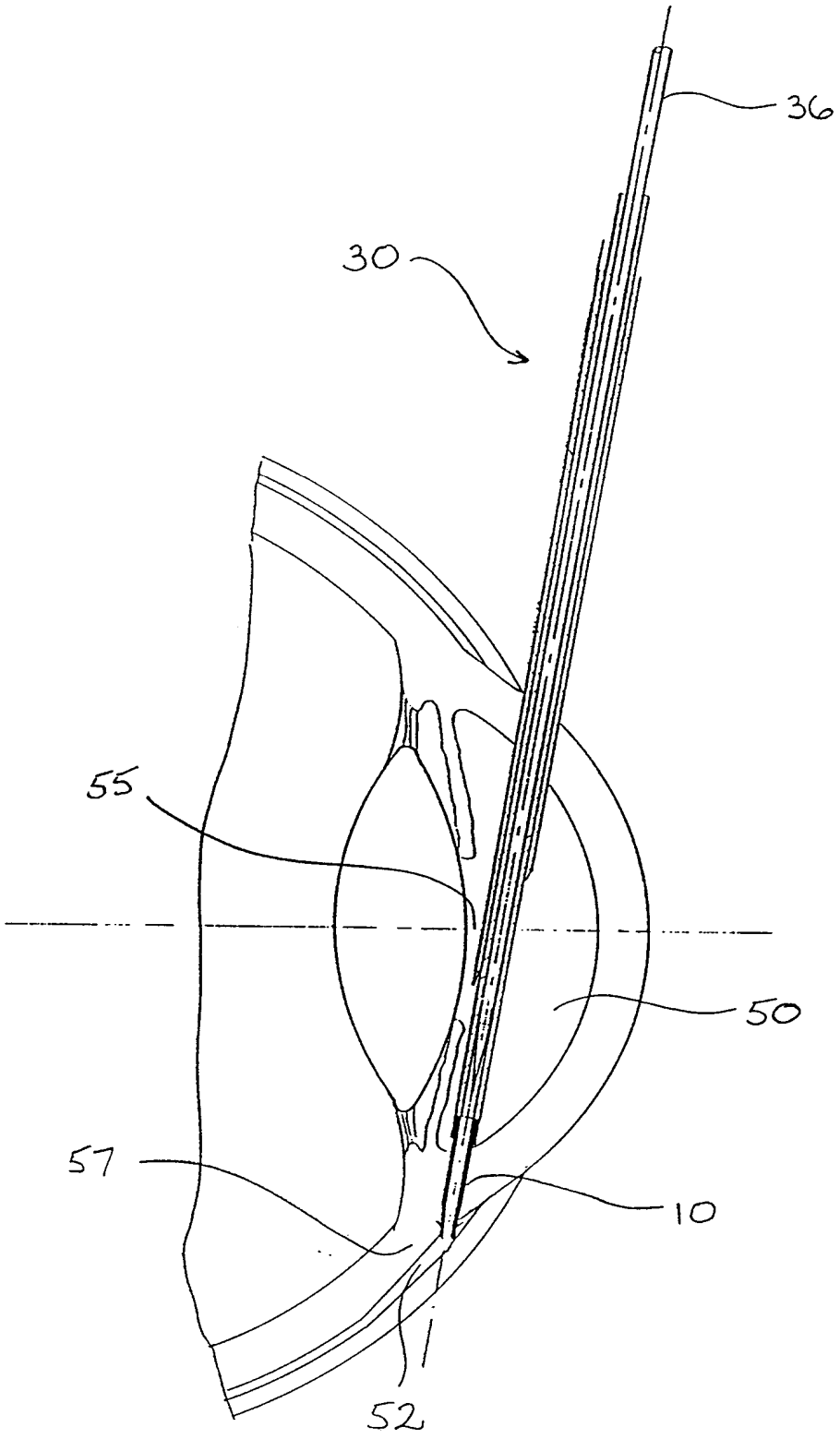


FIGURE 5



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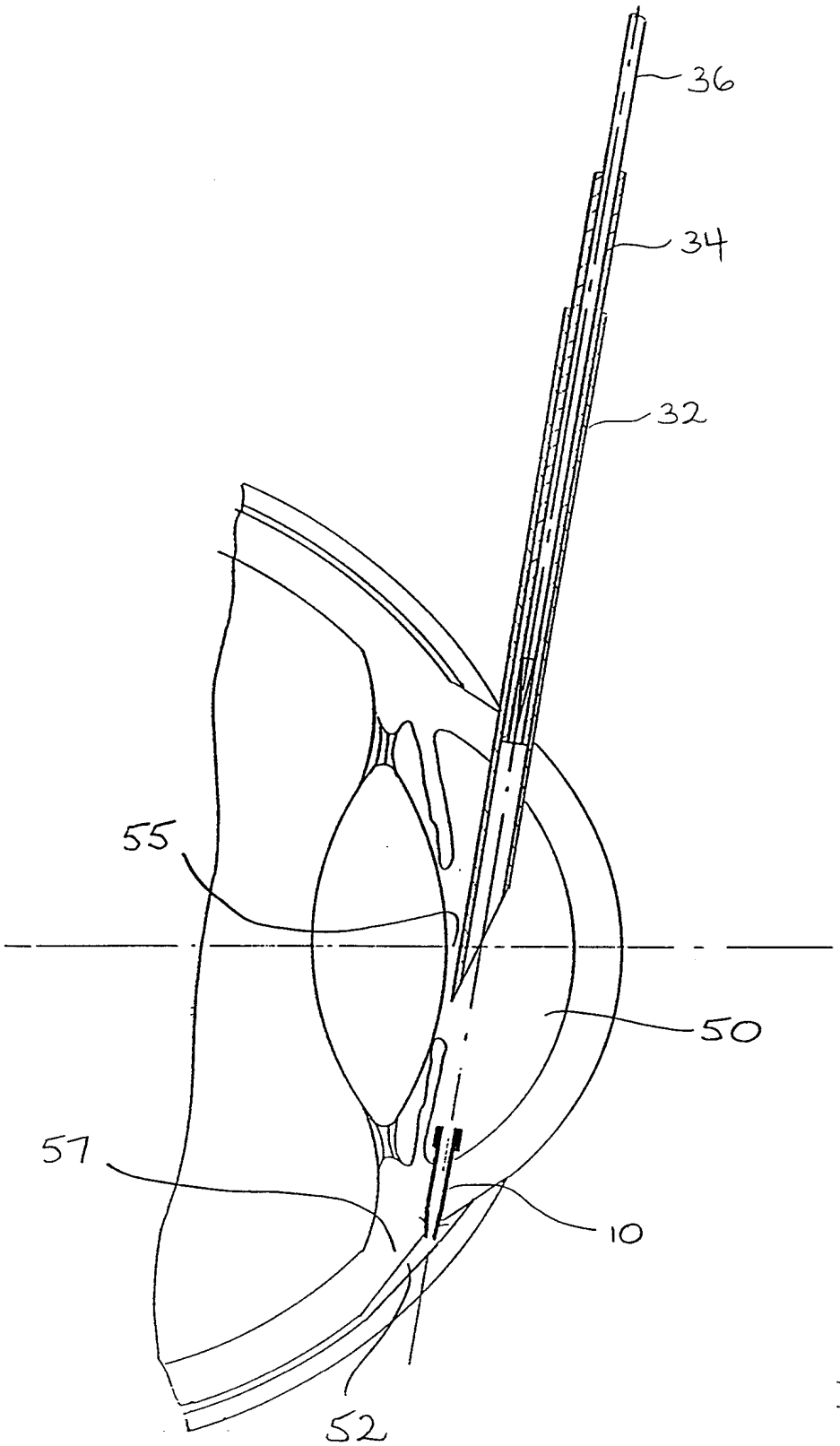

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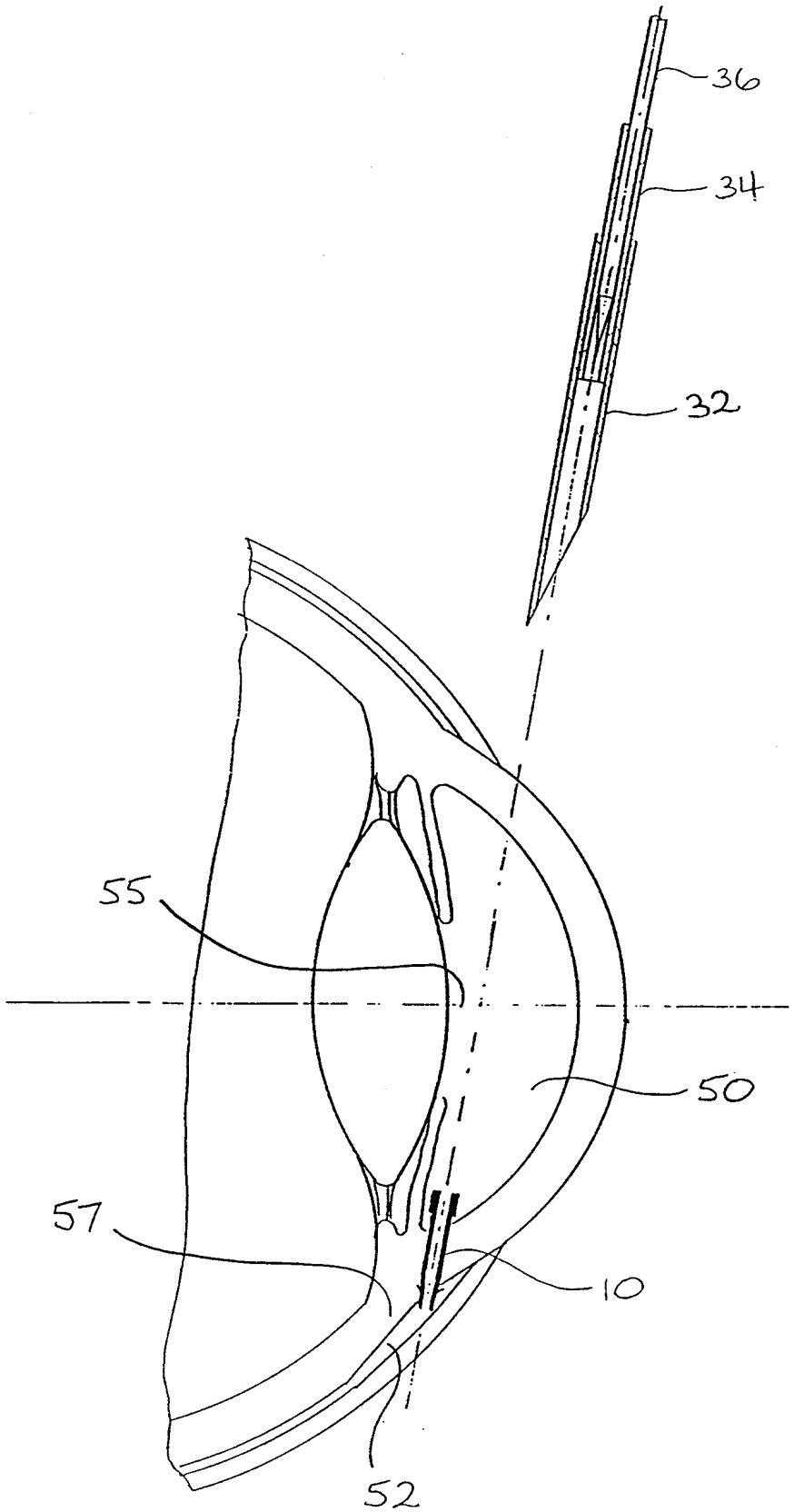


FIGURE 8

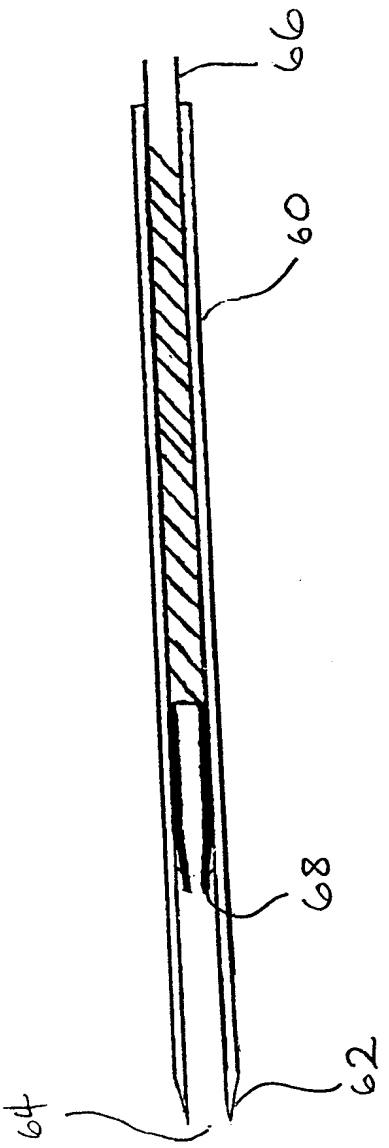


FIGURE 9

FIGURE 10

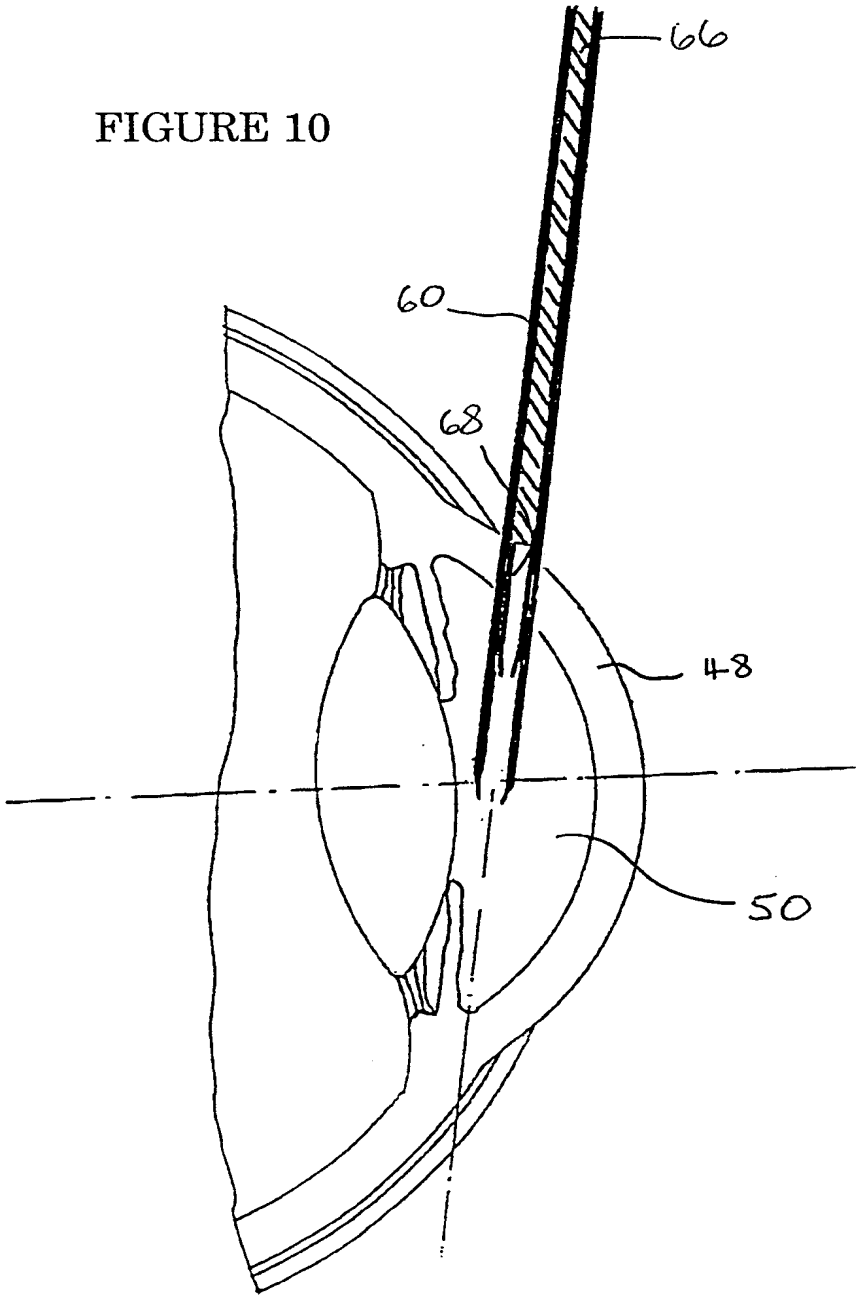
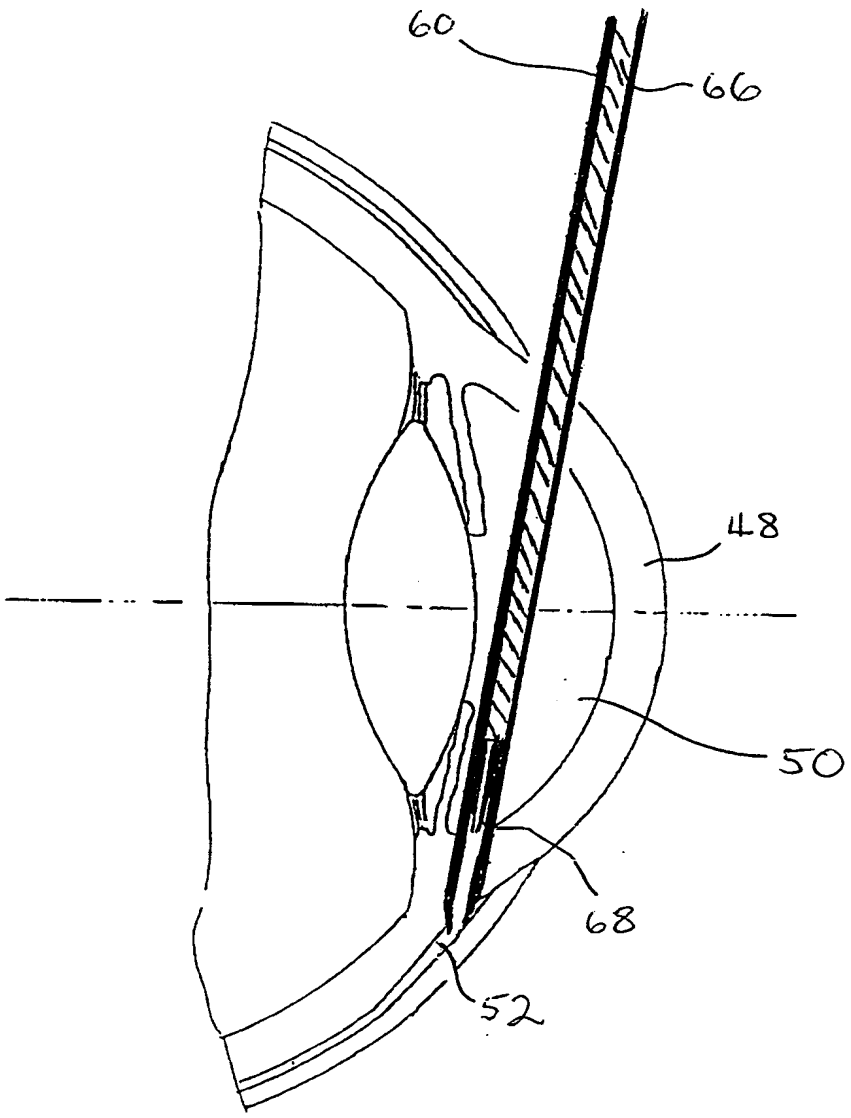


FIGURE 11



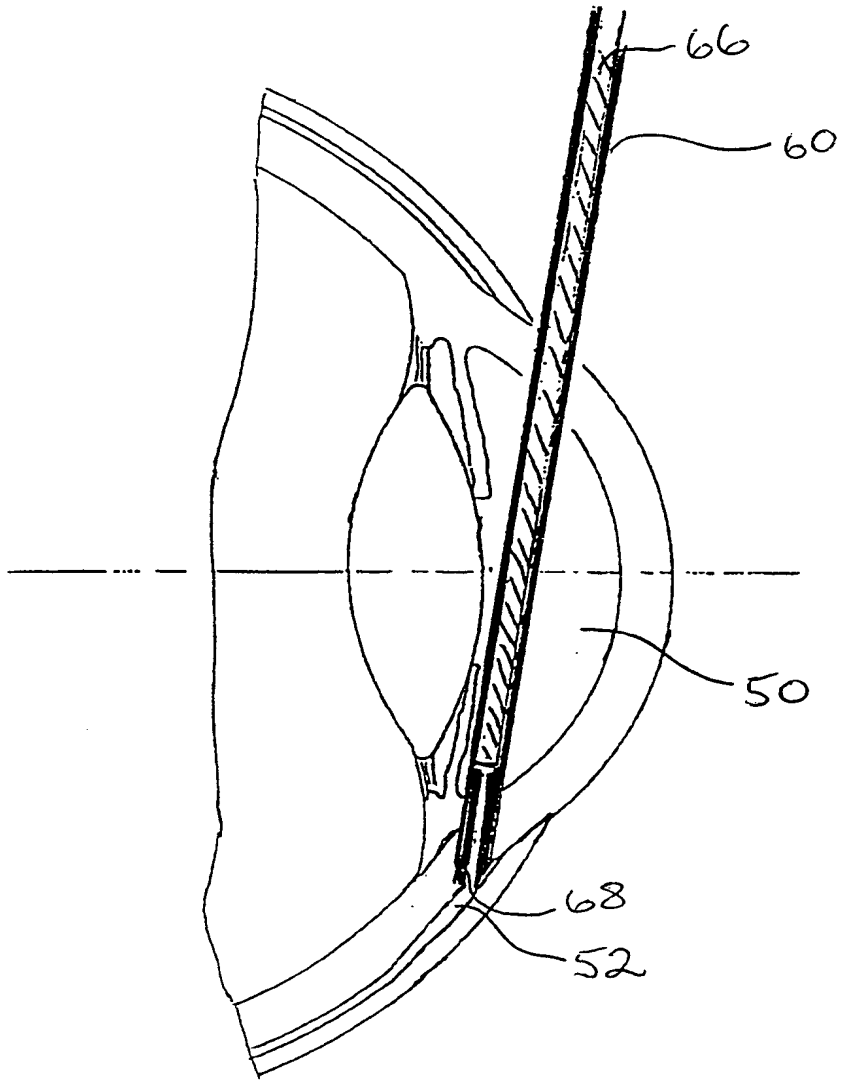


FIGURE 12

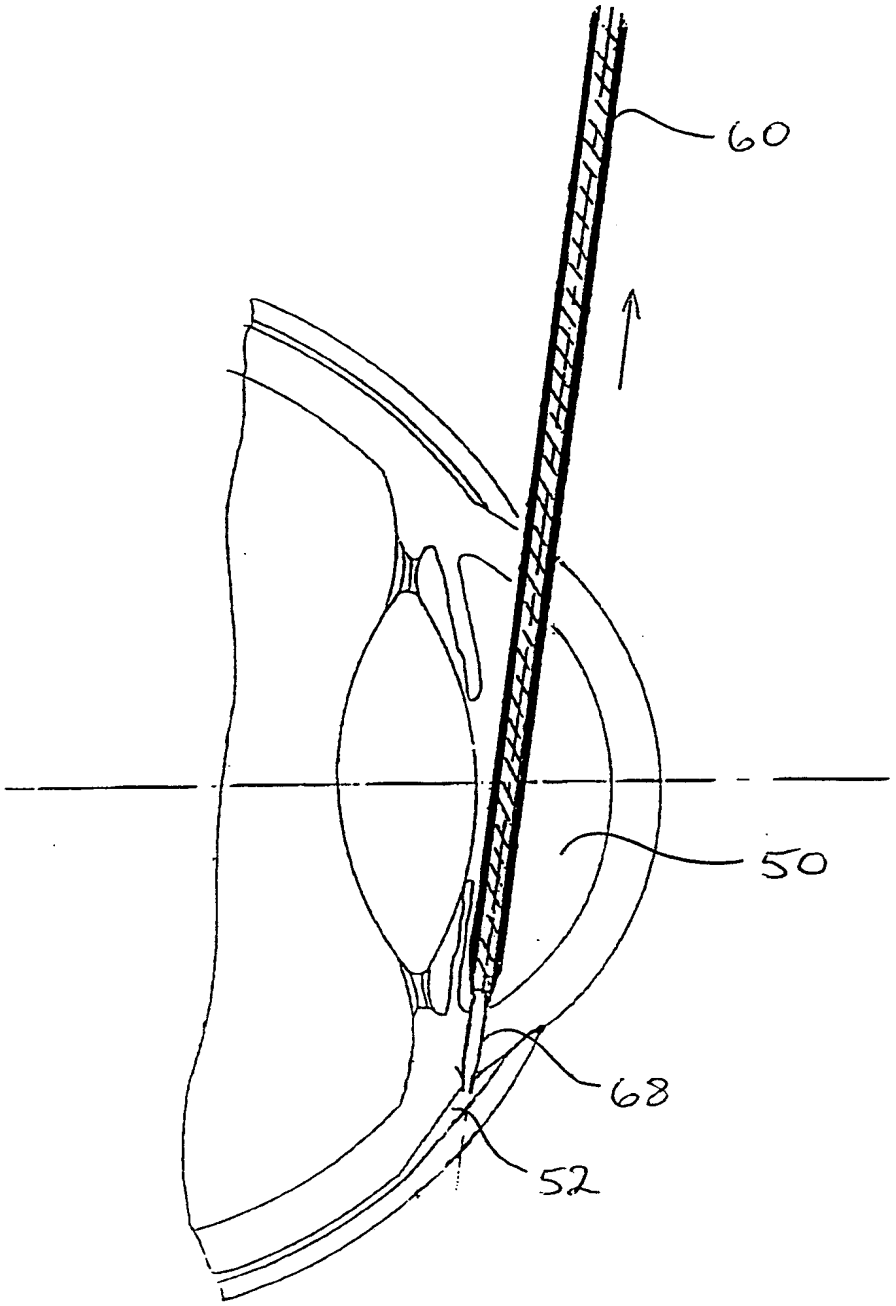


FIGURE 13

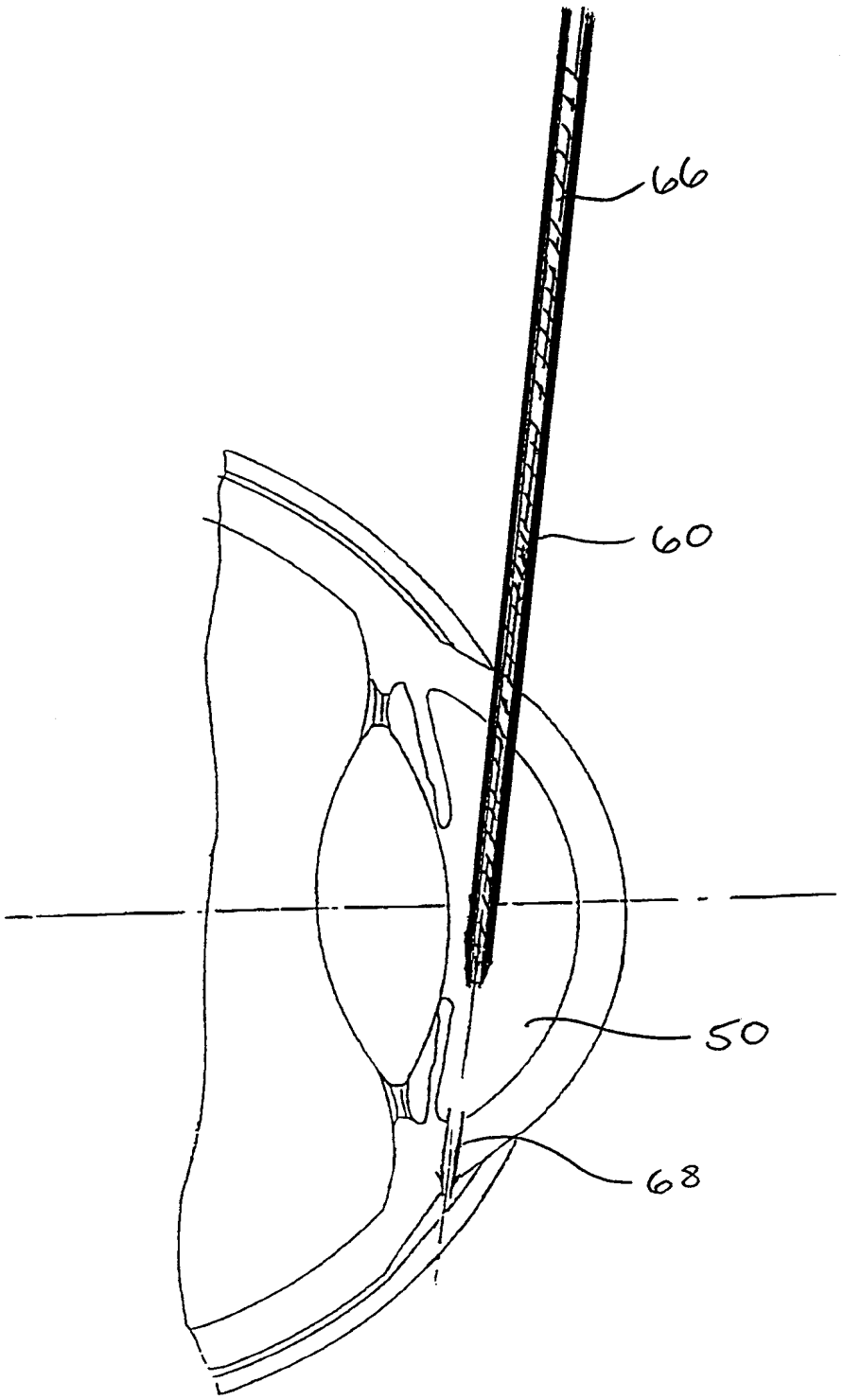


FIGURE 14

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00811

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61F 9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC : A61F 9/007

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT & JAPIO + keywords (microfistula, fistula, tube, canal, duct, pipe, channel, tubular, passage, coat: membrane, skin, shell, cover:, matrix, mesh, soluble, solubility, absorb:, eye, ocular, glaucoma, intraocular)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94/13234 A1 (COOTE, Michael Andrew) 23 June 1994	
A	GB 2296663 A (AHMED SALIH MAHMUD) 10 July 1996	
A	WO 95/08310 A1 (PITHON, Francois) 30 March 1995	

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 December 1997	13 JAN 1998
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer **GEOFF SADLIER** Telephone No.: (02) 6283 2114

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00811

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5516522 A (PEYMAN et al.) 14 May 1996	
A	US 4863457 A (LEE) 5 September 1989	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 97/00811

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	94/13234	AU	66531/94		
WO	9508310	AU	75455/94	FR	2710269

END OF ANNEX